PTO/SB/08A (10-96)
Approved for use through 10/31/99, OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

	Under the Paperwork	Reduction Act of	1995, no persons	are required to	respond to a collection of information	on unless it displays a valid OMB control numb
OF	Substitut	e for form 1449A	/PTO		Comp	olete if Known
6× -	4ARS SUBSTITUTE				Application Number	10/747,686
· .	1 2008 WINFO	RMATION	DISCLOSE	JRE	Filing Date	December 30, 2003
MAR 1	1 1000 BINFO	EMENT B	Y APPLICA	ANT	First Named Inventor	STEINER, Mitchell S.
					Art Unit	1618
TENTO	THATELUSE (US	e as many shee	ts as necessar	y)	Examiner Name	Fubara, Blessing M
_	Sheet	1	of	11	Attorney Docket Number	P-2769-US9

			U.S. PATENT DOCUMENT	TS	
xaminer nitials*	Cite, No.	U.S. Patent Docur Number Kind (if kno	Name of Patentee or Applican Code ² of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/BF/	A	4,990,538	Harris et al.	February 5, 91	
	В	5,788,964	Baral et al.	August 4, 98	
	С	5,650,425	Biegnon et al.	July 22, 97	
	D	4,696,949	Toivola et al.	Sept 29, 87	
	E	5,491,173	Toivola et al.	Feb. 13, 1996	
	F	5,571,534	Jalonen et al.	Nov. 5, 1996	
	G	5,605,700	DeGregorio et al.	Feb. 25, 1997	
	н	5,595,722	Grainger et al.	Jan. 21, 1997	
	1	5,599,844	Grainger et al.	Feb. 4, 1997	
	J	5,629,007	Audia et al.	May 13, 1997	
	K	5,635,197	Audia et al.	June 3, 1997	
	L	5,595,985	Labrie	Jan. 21, 1997	
	M	5,441,986	Thompson, et al	08-15-1995	
	N	5,852,059	Thompson, et al	12-22-1998	
	0	5,827,892	Loeser, et al	10-27-1998	
\neg	Р	5,821,254	Sporn, et al	10-13-1998	
	Q	5,859,045	Treppendahl, et al	01-12-1999	
1/	R	5,935,987	Treppendahl, et al	08-10-1999	
V	s	5,763,415	Sukumar, Saraswati	06-1998	
/BF/	т	5,916,916	Hauser et al	06-1999	

	T	Fore	ignPatent Document		Date of Publication of	1	T
Examiner Cite Initials* No.		Office ³ Number ⁴ (if known)		Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
./BF/	U	wo	98/58634	Degregorio et al	December 30, 98		-
I	V	EP	415 623 A2	Harris et al	March 6, 1991	1	
	w	EP	616 529 B1	Heikkila et al	September 28, 94		
T	×	EP	095875	Toivola et al	Dec 7, 1983		
1/	Y	wo	95/26720	Biegon et al	Oct 12, 1995		
(00)	z	wo	00/08001	Huebner et al	Feb 17, 2000		

Examiner Signature	/Blessing Fubara/	Date Considered	12/05/2006
	eference considered, whether or not citation is in copy of this form with next communication to applicant		line through citation if not in conformance and no

considered, include copy of the torm with "See all active flows of U.S. Patient Documents." Enter Office has its asset the document with the seed of U.S. Patient Documents. "Enter Office has it because the document country in the reveloped of the Common of the Common

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Planet and Trademan Office, Washington. DC 20231-DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assignant Commissioner in Planets. Washington, DC 20231

Under the Paperwork Reduction Act of 1995, no persons are required to res Substitute for form 1449A/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

sporta to a concessor or interment					
Complete if Known					
Application Number	10/747,686				
Filing Date	December 30, 2003				
First Named Inventor	STEINER, Mitchell S.				
Art Unit	1618				
Examiner Name	Fubara, Blessing M				
Attorney Docket Number	P-2769-US9				

		U.	S. PATENT DOCUMENTS		
Examiner nitials*	Cite Number Kind Code² (if known)		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/BF/	AA	4,329,364	Neri et al.	May 11, 1982	
	AB	4,474,813	Neri et al.	Oct. 2, 1984	
	AC	6,080,877	Swindell et al	June, 2000	
	AD	6,265,448	Steiner et al	July 24, 2001	
	AE	6,410,043	Steiner et al	June 25, 2002	
	AF	6,632,447	Steiner et al	Oct 14, 2003	
	AG	6,413,533	Steiner et al	July 2, 2002	
	АН	6,413,534	Steiner et al	July 2, 2002	
	AI	6,413,535	Steiner et al	July 2, 2002	
	AJ	4,996,225	Toivola et al	Feb 26, 1991	
	AK	5,811,120	Gibson et al	Sept 22, 1998	
	AL	5,972,383	Gibson et al	Oct 26, 1999	
	AM	4,418,068	Jones	Nov 29, 1983	
1,	AN	5,728,707	Wehrmann	Mar 17, 199	8
V	AO	6,899,888	Steiner et al	05-2005	
/BF/	AP	6,569,896	Dalton et al	12-1998	1

11

			F	ORE	GN PATENT DOCUME	NTS		
Examiner Initials*	Cite, No	ForeignPatent Document Office ³ Number Kind Code ⁵ (if known)			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т
/BF/	AQ	wo	94/12162		Warri et al	June 9, 1994		E
T	AR	wo	99/56739		Steiner et al	November 11, 1999		Ic
1	AS	wo	00/47214		Healey et al	August 17, 2000		:0
1	AT	wo	95/09046		Audia et al	March 28, 1996		Ĺ
1	AU	EP	0 670 162	1	Gibson et al	Sept 6, 1995		_;[
	AV	wo	00/19998		KGK Synergize	04-13-2000		ļc
1	AW	wo	97/25038		Novo Nordisk	7-17-1997		!C
1	AX	wo	99/08682		Duke University	02-25-1999		ı
	AY	wo	97/25037		Novo Nordisk	7-17-1997		
Λ	AZ	wo	97/03046		Bohlmann et al	01-30-1997		1
/BET	BA	wo	98/045288		Neubauer et al	10-1998		

Signature	/Blessing Fubara/	Considered	12/05/2008
*EXAMINER: Initial if refer considered. Include copy of	ence considered, whether or not citation is in confo of this form with next communication to applicant.	rmance with MPEP 609. Draw line	through citation if not in conformance and not

Date

^{*}Unique classing alon number. * See attached Kinds of U.S. Patent Documents. * Enter Office that issued the document, by the two-inter code (WIPO Standard ST.3). * For Japanese partie document, the recication of the year of the reign of the Emperor must precide the senial number of the patent document. * For Japanese partie document, the document with the patent document. * Control of Standard ST.3. * The Tapanese partie that the patent document under WIPO Standard ST. 15 if peedite. * Applicant is in place a check mark the of English language than standard ST. 15 if peedite. * Applicant is in place a check mark the of English language than standard ST. 15 if peedite. * Applicant is in place a check mark the of English language than standard ST. 15 if peedite. * Applicant is in place a check mark the of English language than standard ST. 15 if peedite. * Applicant is in place a check mark the of English language than standard ST. 15 if peedite. * Applicant is in place a check mark the of English language that standard ST. 15 if peedite. * Applicant is in place a check mark the of the English language that standard ST. 15 if peedite. * Applicant is in place a check mark the original standard ST. 15 if peedite is a standard ST. 15 if peedite. * Applicant is in place a check mark the original standard ST. 15 if peedite. * Applicant is in place a check mark that the original standard ST. 15 is peedited. * Applicant is in place a check mark that the original standard ST. 15 is peedited. * Applicant is in place a check mark that the original standard ST. 15 is peedited. * Applicant is in place a check mark that the original standard ST. 15 is peedited. * Applicant is in place a check mark that the original standard ST. 15 is peedited. * Applicant is in place a check mark that the original standard ST. 15 is peedited. * Applicant is in place a check mark that the original standard ST. 15 is peedited. * Applicant is peed to the original standard ST. 15 is peedited. * Applicant is peedited. * Applicant is peedited. * Ap

Approved for use through 10/31/99 OMB 0551-0031

Patent and Trademark Office. U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Subst	tute for form 1449/	VPTO		Complete if Known		
				Application Number	10/747,686	
INF	ORMATION	DISCLOS	JRE	Filing Date	December 30, 2003	
ST	ATEMENT B	Y APPLICA	ANT	First Named Inventor	STEINER, Mitchell S.	
				Art Unit	1618	
	use as many she	ets as necessar	y)	Examiner Name	Fubara, Blessing M	
Sheet	3	of	11	Attorney Docket Number	P-2769-US9	

U.S. PATENT DOCUMENTS							
Examiner nitials*	Cite, No.1	U.S. Patent Document Number Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
/8F/	BB	US 2006/0019989	Steiner et al	01-2006			
/BF/	BC	US 2005/0171073	Steiner et al	08-2005			
Reconstruction		US 2004/0186185	Stemer et al	09-2004	1		
/BF/	BE	US 2005/0080143	Steiner et al	04-2005			
1	BF	US 2006/0270641	Steiner et al	11-2006			
1/	BG	US 2004/0176470	Steiner et al	09-2004			
V	ВН	US 2004/0096510	Steiner et al	05-2004			
/BF/	BI	US 2003/0153625	Steiner et al	08-2003			
	T						
	1						
	+						
							
	+	 		+			
			1	1			

	Examiner	/Blessing Fubars/	Date
1	Signature		Considered 12/05/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

considered, include copy of this form with next communication to applicant.

'Include claims designation number.' See attained fusion of U.S. Patent Documents.' Include rife, an all issued the document, by the two letter concluded the second of the patent document. In the patent document is present and the patent document is present document.' Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST, 16 if possible. "Applicant is to place a check mark here if English language Translation is attached."

Surden Hour Statement: This form is estimated to take 20 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Platent and Tratemant Office. Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO. Assistant Commissioner for Patients, Washington, DC 20231.

^{*}Examined Application is not prior art

Please type a plus sign (+) inside this box -> | + | FT.O/SB/B8.4 (10.48)
Approved for use through 10.3189 (30.48)
Approved for use through 10.3189 (30.48)
Patent and Tademark Office: U.S. DEFARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless 2 displays a valide control number.

Su	bstitute for form 1449/	VPTO		Complete if Known		
				Application Number	10/747,686	
11	NFORMATION	DISCLOSE	JRE	Filing Date	December 30, 2003	
S	TATEMENT B	Y APPLICA	ANT	First Named Inventor	STEINER, Mitchell S.	
				Art Unit	1618	
	(use as many she	ets as necessar	y)	Examiner Name	Fubara, Blessing M	
Sheet	4	of	11	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS						
Examiner nitials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²					
/BF/ BJ		Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", In J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107.						
1	BK	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.						
	BL	Kelloff et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 16H: 1-8.						
		Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxypheny)/retinamide, and the Vitamin D Analogue Ro24-553 1 for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.						
	1	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.						
	во	Schneider Martin R. et al. "Nonsteroidal Antiestrogens and Partial Estrogens with Prostatic Turnor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 259-265, p. 258-265,						
	BP	Martel Celine et al. "Binding Characteristics of Novel Nonsteroidal Antestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J. Sterold Biochem. Molec. Bio. Vol 64, No. 3-4, pp. 199-205, 1998.						
	BQ	Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.	P					
	BR	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997						
	BS	Christian Rohlff et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Linase C and Induction of p21" The Prostate 37:51-59 (1998) @1998 Wiley-Liss, Inc						
	ВТ	Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Ress, vol. 53, no. 21, 1993, pages 5199-5207, XO002117653.						
	BU	Gingrich et al., "Androgen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691.						
T	BV	Gingrich et al., "Pathalogic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75.						
1	BW	Gingrich et al., "Metastatic Prostrate Cancer in a Transgenic Mouse", in Cancer Research 56, September 15, 1996, pages 4096-4102.						
/BF/	BX	Gershanovich et al., "A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262.						

Examiner		Date	
Examine	Miles and the Product of		
Signature 1	/Blessing Fubara/	Considered	

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this from should be sent to the Chief Information Officer, Patient and Trademan Officer, Washington, DC 20231. DO NOT SEND PEES OR COMPLETED PORNS TO THIS ADDRESS. SEND TO Assistant Commissioner for Patients, Washington, DC 20231.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English tanguage Translation is attached.

Substitu	te for form 1449A	/PTO		Complete if Known		
				Application Number	10/747,686	
INFO	RMATION	DISCLOS	URE	Filing Date	December 30, 2003	
STA	TEMENT B	Y APPLIC	ANT	First Named Inventor	STEINER, Mitchell S.	
				Art Unit	1618	
(u	se as many shee	ts as necessar	y)	Examiner Name	Fubara, Blessing M	
Sheet	5	of	11	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
xaminer	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/BF/	BY	Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of Toremifenein Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical Oncology, Vol. 13, No. 10, 1995, pages 2556-2566.	
	BZ	Pyrhönen et al., "Comparison of Toremifene and Tamoxifen in Postmenopausal Patients with Advanced Breast Cancer: a Randomized Double-blind, the 'Nordic' Phase III Study', British Journal of Cancer, 1997, 76(2), pages 270-277.	
	CA	Neubauer et al., "Endocrine and Antiprostatic Effects of Raloxifene (LY156758) in the Male Rat". The Prostate 23, 1993, pages 245-262.	
	СВ	Pollard, "Prevention of Prostate-Related Cancers in Lobund-Wistar Rats", The Prostate 39, 1999, pages 305-309.	
	СС	Simard et al., "Keoxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs", Molecular and Cellular Endocrinology 39, 1985, pages 141-144.	
		Perry "High Dose Toremifene for Estrogen and Progesterone Receptor Negative Metastatic Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast Cancer Res Treat - 1995; 26(1): 25-40	
	i	Hietanen T "Open Phase II Study of High-Dose Toremifene as First-Line Therapy for Advanced Breast Cancer" in Oncology - May 1997; 11(5 Suppl 4): 37-40.	T
	CF	Black et al. "Uterine Bioassay of Tamoxifen, Trioxifene and a New Estrogen Antogonist (LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458	
	CG	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by 17β- Estadior, in J. Ciln. Invest. © The American Society for Clinical Investigation, Inc., Vol. 63 March 1979, pages 351-357.	
	СН	Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4- Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994)	
	CI	Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.	
	CJ	Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer, pages 467-477	
	CK	Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271	
	CL	Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen Toremifene In Sprague-Dawley Rats" Drug Chem Toxicol 1996 Nov; 19(4): 245-66.	
1,	СМ	Powles TJ "Status Of Antiestrogen Breast Cancer Prevention Tnals" Oncology (Huntingt) 1998 Mar; 12(3 Suppl 5): 28-31.	
/BF/	CN	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifon, Aminoglutethimide and Procesterone". Anticancer Res 1994 May-June; 14(3a), 889-93.	

Examiner		Date	
Signature	/Blessing Fubara/	Considered	12/05/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement. This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Cale Information Officer, Patent and Tademark Office, Waishington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO Assistant Commissioner for Patents, Waishington DC 20231.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO				Complete if Known		
				Application Number	10/747,686	
INFO	INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Filing Date	December 30, 2003	
STA				First Named Inventor	STEINER, Mitchell S.	
				Art Unit	1618	
(use as many sheets as necessary))	Examiner Name	Fubara, Blessing M	
Sheet	6	of	11	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite		Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/BF/ CO		Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dorsal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88.	
	CP	Foekens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", Br J Cancer 1999 Feb; 79(5- 6); 888-94.	
	CO	Brandes LJ et al. "Salutary Clinical Response Of Prostate Cancer To Antiandrogen Withdrawal: Assessment Of Flutamide In An In Vitro Paragdigm Predictive Of Tumor Growth Enhancement", Clin Cancer Res 1997 Aug; 3(8): 1357-61.	
	CR	Miyata E et al. "Effects Of Tamoxifen, An Antiestrogen, On Rat Prostate Carcinogenesis by 3,2-Dimethyl-4-Aminobiphenyl And Testerone Do Not Support An Estrogen Role In Testerone Promotion", Prostate 1997 Apr 1;31(1)9-13.	
	cs	Pients KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate"., Am J Clin Oncol 1996 Oct; 19(5):500-3.	
	СТ	Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate1995 May; 26(5): 270-4.	
	CU	Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73.	
	CV	Szarka CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79.	
	cw	Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen In Patients With Hormone- Refractory Prostate Cancer." Clin Cancer Res 1999 Sep; 5(9): 2366-73.	
	СХ	Chang William Y et al. "Estrogen Receptor-β: Implications For The Prostate Gland" The Prostate 40:115-124 (1999)	
	CY	Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor-α (Er-α) And β (Er-β) mRNA in The Rat Pituitary, Gonad, And Reproductive Tract" Steroids 63: 498-504, 1998, Elsevier Science Inc.	
	cz	Prins Gail S. et al, "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression in The Developing And Adult Rat Prostate Lobes", Endocrinology 138: 1801-1809, 1997)	
1	DA	Hempstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto-Oestrogens", British Journal Of Urology (1998). 82. 560-563.	1
V	DB	Awoniyi Caleb A. et al. "Neonatal Exposure To Coumestrol, A Phystoestrogen, Does Not Alter Spermatogenic Potential In Rats", Endocrine, vol. 7, no. 3, 337-341, December 1997.	
/BF/	DC	"Chemoprevention Of Prostate Cancer: Guidelines For Possible Intervention Strategies", Journal of Cellular Biochemistry, Supplement 16H:140-145 (1992).	

Examiner		Date	40/05/0000
Signature	/Blessing Fubara/	Considered	12/05/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademan Office. Weshington, DC 20231. DO NOT SEND PEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO Assistant Commissioner for Patents, Washington, DC 20231.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substi	tute for form 1449.	A/PTO		Complete if Known		
				Application Number	10/747,686	
INF	ORMATION	DISCLOS	JRE	Filing Date	December 30, 2003	
STA	ATEMENT E	Y APPLICA	ANT	First Named Inventor	STEINER, Mitchell S.	
				Art Unit	1618	
	use as many she	ets as necessar	y)	Examiner Name	Fubara, Blessing M	
Sheet	7	of	11	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	_
xaminer	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/BF/ DD		"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 16H:138- 139 (1992).	
		"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER-β", Endocrinology Vol. 138, No. 3, (1997).	
	DF	Kuiper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcript Tissue Distribution Of Estrogen Receptors α and β", Endocrinology Vol. 138, No. 3, 863-870 (1997).	
	DG	Colletta Anthony A. et al. "Alternative Mechanisms Of Action Of Anti-Oestrogens" Breast Cancer Research and Treatment 31: 5-9, 1994.	
		Griffiths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme.	
	DI	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3)291-300.	
	DJ	Horton J et al. "Tamoxifen In Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7.	
	DK	Kangas L "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.	
	DL	Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35.	
	DM	Kamat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161. 1748-1760. June 1999, p. 1748-1760.	
	DN	Fleton SA "Potential New Antiestrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52	
	DO	Nevalainen M.T. et al. "Estrogen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618	
	DP	Moon R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modiflers: Torernifene. RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Research 14: 888-984 (1994)	
/8F/	DQ	Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106.	

Examiner Signature	/Blessing Fubara/	Date Considered	12/05/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant,

Burden Hour Statement. This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Celle Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO. Assistant Commissioner for Patents, Washington, DC 20231.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box --> + + PT_0158.08.4 (10.46)
Approved for use through 103.1198, 0MB 654.0301
Patent and Tademark Office: U.S. DEFARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless 8 displays a valide Southly another.

Substi	tute for form 1449/	VPTO		Complete if Known		
				Application Number	10/747,686	
INF	ORMATION	DISCLOSE	JRE	Filing Date	December 30, 2003	
STA	ATEMENT B	Y APPLICA	ANT	First Named Inventor	STEINER, Mitchell S.	
				Art Unit	1618	
(use as many she	ets as necessar	y)	Examiner Name	Fubara, Blessing M	
Sheet	8	of	11	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
xaminer nitials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/BF/	DR	Cheng E et al. "Endocrinology Of The Prostate", Prostate Diseases, chapter 5- p. 57-71.	
	DS	Bonkhoff H et al. "Estrogen Receptor Expression In Prostate Cancer and Premalignant Prosatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999.	
	DT	"New Research Approaches In The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research. December 1998	
	DU	Xiaolin Zi et al. "Silibinin Decreases Prostate-Specific Antigen With Cell Growth Inhibition Via G1 Arrest, Leading To Differentiation Of Prostate Carcinoma Cells: Implications For Prostate Cancin Intervention., Proc. Nsil. Acad. Sci. USA VO. 96, pp. 7499-7495, June 1999. Medical Sciences.	
	DV	Landstrom M, et al. "Inhibitory Effects Of Soy and Rye Diets On The Development Of Dunning R3327 Prostate Adenocarcinoma in Rats, The Prostate 36: 151-161 (1998).	
	DW	Buelke-Sam J. et al. "The Selective Estrogen Receptor Modulator, Ratoxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1988 May-June; 12(3):217-21.	
	DX	Treinen KA et al. "An Evaluation Of The Novel Selective Estrogen Receptor Modulator, Idoxifene, For Effects On Reproduction In Rats And Rabbits:, Toxicol Sci 1998 Feb; 41(2):199-207.	
	DY	Boehm S et al. "Estrogen Suppression As A Pharmacotherapeutic Strategy In The Medical Treatment Of Benign Prostatic Hyperplasia: Evidence For Its Efficacy From Studies With Mepartnicin Vinen Klin Wochenschr 1998 Dec 11, 110(23):817-23.	
	DZ	Dhar JD et al. "Estrogen, Androgen and Antiestrogen Responses In The Accessory Organs Of Male Rats During Different Phases Of Life", Endocr Res 1998 May; 24(2): 159-69.	
	EA	West Neal B et al. "Estrogen and Progestin Receptors And Aromatase Activity In Rhesus Monkey Prostate" Endocrinology, Vol. L. 123, (1998)	
V	EB	Strauss L "Genistein Exerts Estrogen-Like Effects In Male Mouse Reproductive Tract", Molecular and Cellular Endocrinology 144 (1998) 83-93, Elsevier Science Ireland Ltd.	

Examiner Date 12/05/2008		 	
Signature	Signature	Considered	12002000

^{*} EXAMINER: initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw tine through citation if not in conformance and not considered, Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to compilete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to compilete this form should be sent to the Chife Information Officer. Plantet and Trademark Office. Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO. Assistant Commissioner for Patients, Washington and Chife Chife

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substit	ute for form 1449.	A/PTO		Complete if Known				
				Application Number 10/747,686				
INFO	ORMATION	DISCLOSE	JRE	Filing Date	December 30, 2003			
STA	TEMENT E	Y APPLICA	ANT	First Named Inventor	STEINER, Mitchell S.			
				Art Unit	1618			
(1	ise as many she	ets as necessar	y)	Examiner Name	Fubara, Blessing M			
Sheet	9	of	11	Attorney Docket Number	P-2769-US9			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/BF/	EC	Hobisch Alfred "Metastatic Lesions From Prostate Cancer Do Not Express Oestrogen And Progesterone Receptors" J. Pathol. 182: 356-361, 1997.	
	ED	Albert David S. et al. "An Overview Of Clinical Cancer Chemoprevention Studies With Emphasis On Positive Phase III Studies" Overivew of Diet Cancer 6928-6975 (1995)	
	EF	Strom Sara S. et al. "Phytoestrogen Intake and Prostate Cancer: A Case-Control Study Using A New Database", Nutrition and Cancer, 33(1), 20-25. (1999).	
	EG	Kellof GJ et al "Strategies For Chemoprevention Of Prostate Cancer", Prostate Cancer and Prostate Disease (1988) 5. 107.	
	EH	Buelke-Sam Judy et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology and Reproductive Development Testing", Reproductive Toxicology Vol. 12, No. 3 pp. 217-221, 1998.	
	EI	Prins Gail S. "Developmental Estrogenization Of The Prostate Gland", Prostate:Basic and Clinical Aspects p. 245-263 (1997).	
	EJ	Kulper George G. J. M. "Cloning Of A Novel Estrogen Receptor Expressed In Rat Prostate And Ovary", Proc. Natl. Acad. Sci USA Vol. 93, pp. 5925-5930, June 1996 Biochemistry.	
	EK	Kulper George G. J. M. "Interaction Of Estrogenic Chemicals and Phytoestrogens With Estrogen Receptor β", Endocrinology Vol. 139, No. 10 (1998).	
	EL	Horton John et al. "Tamoxifen In Advanced Prostate Cancer" An ECOG Pilot Study", The Prostate 12: 173-177 (1988).	
	ЕМ	Hayes "A Randomized Comparison Of Tamoxifen, Trioxifene And A New Estrogen Antogonist (LY117018) In Rats And Mice" In Life Sciences, 1980, vol. 26, pp. 1453-1458.	
	EN	Jordan Craig V. "Antiestrogenic Action of Raloxifene and Tamoxifen: Today and Tomorrow" Journal of National Cancer Institute, Vol. 90, No. 13, July 1, 1998	
	EO	Warri Anni. M. et al "Apoptosis in Toremifene Induced Growth Inhibition of Human Breast Cancer Cells in Vivo and In Vitro" Journal of National Cancer Institute, Vol. 85, No. 17. September 1, 1993	
\downarrow	EP	Mobbs, B.G. et al "Concentration and Cellular Distribution of Androgen Receptor in Human Prostatic Neoplesia: Can Estrogen Treatment Increase Androgen Receptor Content?" J. Steroid Biochem. Vol. 19, No. 3 pp. 1279-1290, 1987.	
/BF/	EQ	Kneg, Michael et al "Androgens and Estrogens: Their Interaction with Stroma and Epithelium of Human Benign Prostatic Hyperplasia and Normal Prostate" J. Steroid Biochem. Vol. 19, No. 1 pp. 155-161, 1983	

Examiner	/Blessing Fubara/	Date 12/05/2008 Considered
Signature	10-cooling 1 abarar	Considered

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Thine will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chel Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO PIAS ADDRESS. SEND TO, Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to a

Subs	titute for form 1449/	N/PTO		Complete if Known			
				Application Number	10/747,686		
INF	ORMATION	DISCLOSE	URE	Filing Date December 30, 2003			
ST	ATEMENT B	Y APPLICA	ANT	First Named Inventor	STEINER, Mitchell S.		
				Art Unit	1618		
	(use as many she	ets as necessar	y)	Examiner Name	Fubara, Blessing M		
Sheet	10	of	11	Attorney Docket Number	P-2769-US9		

		NON PATENT LITERATURE DOCUMENTS	
xaminer	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, senial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where publisher.	T²
/BF/	ER	Hard, Gordon C. et al. "Major Difference in the Hepatocarcinogenicity and DNA Adduct Forming Ability between Toremifene and Tamoxifen in Fernale Crl: CD(BR) Rats" Cancer Research 5.4 654-6541. October 1, 1993	
	ES	Boyle Peter et al "Epidemiology of Prostate Cancer Chemoprevention" Eur Urol 1999: 35:370- 376	
1	ET	Bostwick, David G. et al "Reversibility of Prostatic Intraepithelial Neoplasia: Implications for Chemoprevention" Eur. Urol 1999: 35:492-495	
+	ÎEU	Bostwick David "Prospective Origins of Prostate Carcinoma" American Cancer Society 1996	
1	EV	The Lancet "The Challenge of Breast Cancer" Vol. 342, September 18, 1993	
	EW	Zaridze, David G. et al "International Trends in Prostatic Cancer" Int. J. Cancer: 33, 223-230 (1984)	
		Nevalainen MT et al "Hormone regulation of human prostate in organ culture" Cancer Res. 1993 Nov. 1:53 (21):5199-207	
T	1	Treat et al Liposomes in the Therapy of Infectious Disease and Cancer Liss, New York pp. 353-365	
	EZ	Nelson et al (abstract only), "Chemoprevention for prostatic intraepithelial neoplasia", Eur. Urol. 1996;30(2):269-278.	
	FA	Formulary Additions, May, 1998, "Raloxifene (Evieta) 60 mg Tablets"; Pharmacy Key: a publication of the pharmacy and therapeutics committee: formulary additions: http://www.ky.kum.c.du/drujnifo/pharmkey/pharmkey/05/1488.html	
	FB	Frolik et al., "Time-dependent changes in blochemical bone markers and serum cholesterol in ovariextomized rats: effects of raloxifene HCI, tamoxifen, estrogen and alendronate", June 1986; Bone; 18(6): 52/1-627.	
	FC	Sato et al., "Raloxifene: a selective estrogen receptor modulator", Journal of Bone and Mineral Metabolisml 1994; 12(Suppl. 2):S9-S20.	
	FD	Fujimoto et al., "Can we prevent prostate cancer? Rationale and current status of prostate cancer chemoprevention", Urologia Internationalis (2005); 74(4): abstract.	
	FE	Ford et al., "The potential for hormonal prevention trials" Cancer Supplement, November 1994, Vol. 74, No. 9, pages 2725-2733.	
	FF	Steiner et al., "High-grade prostatic intraepithelial neoplasia and prostate cancer risk reductions", World Journal of Urology, 21 May 2003, abstract.	
		Price, "New advances in prostate cancer treatment", American society of Clinica Oncology, 15 May 2005, abstract.	
V	FH	Pylkkanen, et al (1996) "Animal models for the preneoplastic lesions of the prostate" Eur. Urol. 30 (2) 243-8	
/BF/	FI	Raghow, et al (2002) "Toremifene prevents prostate cancer in the trangenice admocarinoma of mouse prostate model." Cancer Research 1;62(5) 1370-6.	

Examiner Signature	/Biessing Fubara/	Date Considered	12/05/2008

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Cabel Information Officer. Pleaset and Trademark Office, Washington DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Pleaset, Washington DC 20231.

⁵ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/OBA (10-86)
Approved for use through 103/19/89, OMB 0551-0031
Patent and Tackmark Office: U.S. DEPATMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unities? 4 displays a valid OMB control number.

Substi	tute for form 1449A	/PTO		Complete if Known				
				Application Number 10/747,686				
INF	ORMATION	DISCLOSE	JRE	Filing Date	December 30, 2003			
STA	ATEMENT B	Y APPLICA	ANT	First Named Inventor	STEINER, Mitchell S.			
				Art Unit	1618			
(use as many she	ets as necessar,	y)	Examiner Name	Fubara, Blessing M			
Sheet	11	of	11	Attorney Docket Number	P-2769-US9			

		NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the	
xaminer nitials*	Cite No.1	include name or the author (in CAPTIAL LET TERS), title of the attitude (whele appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/BF/	1 13	Neubauer, et al (1995) "Raloxifene (LY156758) produces antimetastatic responses and extends survival in the PAIII rat prostatic adencarcinoma model. Prostate 27(4)220-9	
Ī	FK	Black, et al (1983) "Antagonism of estrogen action with a new benzothiophene derived antiestrogen.", Life Sci., 32, 1031-1036	
	FL	Knecht, et al (1985) "Estrogen dependence of luteinizing hormone receptor expression in cultured rat granulosa cells. Inhibition of granulosa cell development by the antiestrogens tamoxifen and keoxifene." Endocrinology, 116, 1771-1777	
	FM	Ortmann, et al (1988) "Inhibitory actions of keoxifene on luteinizing hormone secretion in pituitary gonadotrophs." Endocrinology, 123, 962-968	
	FN	Buchwald et al. (1980) "Long-term, continuous intravenous heparin administration by an implantable influsion pump in ambulatory patients with recurrent venous thrombosis.", Surgery 88:507	
	FO	Saudek et al. (1989) "A preliminary trial of the programmable implantable medication system for insulin delivery.", N. Engl. J. Med. 321:574	
	FP	Langer (1990) "New methods of drug delivery." Science 249:1527-1533	
	FQ	Steiner, et al (2001) Selective estrogen receptor modulators for the chemoprevention of prostate cancer." Urology 57(4 Suppl 1) 68-72	
	FR	Steiner, et al (2003) "Antiestrogens and selective estrogen receptor modulators reduce prostate cancer risk." World Journal of Urology 21(1) 31-6	
	FS	tumor inhibiting activity." 112 (3) 258-65	
V	FT	rat," J. Cancer Res Clin Oncol. 117 (1) 53-6.	
/BF/	FU	Ip MM, et al (1980) "Funtionality of estrogen receptor and tamoxifen treatment of R3327 Dunning rat prostate adenocarcinoma." Cancer Res 40 (7) 2188-93.	ļ.,
	+		-
	士		
	-		<u> </u>
	-		1

Signature	i	/Blessing Fubara/	Considered	12/05/2008
* EXAMINER: Initia	t if refe	rence considered, whether or not citation is in a	onformance with MPEP 609. Draw line thro	ugh citation if not in conformance and not

Date

considered. Include copy of this form with next communication to applicant. ¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chall formation Officer. Planter and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Plants, Washington, DC 20231.

Not Form 1449 Applicant(s)/Patent Under Application/Control No. Reexamination 10/747,686 STEINER ET AL Notice of References Cited Art Unit Examiner Page 1 of Blessing M. Fubara 1618 ILS PATENT DOCUMENTS Date ent Number Name MM-YYYY Country Code US-Α В US-US-С D US-US-E US-F us. c USн 1 US-USĸ US-US-M US-TENT DOCUMENTS FOREIGN F Document Number Country Code-Number-Kind Code Classification Count Name MM-YYYY Ν 0 P Q R s т NON-PATENT DOCUMENTS Ingride as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) ostatic intraepithelial neoplasia and prostate cancer risk reduction, World J. Urology, 21 May 2003, Steiner, "High-grade g abstract. divances in Prostate Cancer Treatment in the American Society of Clinical Oncology, 13 May 2005, abstract. Price, New

'A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Palent and Trademan: Office PTO-892 (Rev. 01-2001) Notice of References Cited

Part of Paper No. 20070815

_	+	TRADEAR			Application/Co	introl No.	Applicant(s Reexamina STEINER E	ition	nt Under
		Notice of Reference	es Cited		11/038,468 Examiner		Art Unit	ET AL.	
		The state of the s			Examinor			1618 Page 1 of 1	
_				ILS P	ATENT DOCUME				
_		Document Number Country Code-Number-Kind Code	Date	T		Name			Classification
1	_		05-2005	Steine	r et al			1	424/423
	Α	US-6,899,888	05-2003	Daltor				17	514/493
	В	US-6,569,896 US-5,852,059	12-1998		pson, David D.				514/648
4	С	US-	12.000	+			. /		
-	D E	US-	1	1				4	
-	F	US-	1				/_	-	
-	G	US-					_/	+	
_	н	US-					/	+	
_	1	US-		<u> </u>		/		+-	
	J	US-		1				+-	
	к	⊍S-		+				+	
_	L.	US-		+-		/		\top	
_	М	US-		FOREIG	N PATENT DOG	OMENTS			
_		Document Number	Date		Country		Name		Classification
*	4_	Country Code-Number-Kind Co	de MM-YYYY	+-	$\overline{}$			-	
_	N			+					
	10			+	/				
	P		-	17					
×	R								
-	s						·		
-	T					<u> </u>	1		
_				NO	N-PATENT DOCU	MENTS	Volume, Pertinent P	anes)	
*			Include as applica	able: Auth	or, Title Date, Put	disher, Edition of	Volume, Grancia	agooj	
Г									
	U		/						
F	-	-						/	
	1							1	
1	1								1
r	+	1							
	V								
Ĺ	Ĺ	1/					·		
Γ	T	X							1
1	1	of this reference is not being furnished MIA-YYYY format are publication de-			m=0 c 707 05(a))				

_	-	MAR 17 2008	i		Application/0 10/611,056	Control No.		Applicant(s)/ Reexaminati STEINER ET	Patent Under on Γ AL.
		Notice of Reference	s Citea		Examiner			Art Unit	Page 1 of 2
١					Blessing M.	Fubara		1618	Tage 1 of 2
	1			U.S. P.	ATENT DOCUM	ENTS			
	_/	Document Number Country Code-Number-Kind Code	Date MM-YYYY			Name			Classification
1	A	US-6,413,534	07-2002	Steiner	r et al.				424/422
7	В	US-8413,533	07-2002	Steine	r et al.				4741422
t	c	US-5,4 3,535	05-1995	Reik, V	Volfgang				474/94
1	D	US-6,410,043	06-2002	Steiner	retal.				424/422
1	E	US-6,265,44%	07-2001	Steine	retal.				514/648
7	F	US-6,632,447	10-2003	Steine	retal.			/	424/434
	G	US-6,899,888	05-2005	Steine	retal.			/_	424/423
	н	US-2006/0019989	01-2006	Steine				/	514/310
	1	US-2005/0171073	08-2005	Steine				/	514/171
	J	US-2004/0186185	09-2004	Steine			/		. 514/651
	к	US-2005/0080143	04-2005	Steine			-/-		514/651
,	L	US-2006/0270641	1-2006	Steine					514/169
	М	US-2004/0176470	09-8004		retal.	/			514/651
_			Date		N PATENT DOO	UMENTS			r
		Document Number Country Code-Number-Kind Code	MM-YYY		Country		Name		Classification
1	N								
Т	0			1					
_	Р								
_	Q.				<u> </u>				
	R				\triangle				
	s		<u> </u>	/					
	т		L	/_					l
_					, Title Date, Pub		or Volume	Particent Page	•\
_	_	Inclu	ide as appricab	ie: Author	, Tibe Date, Pub	PIET, EGIUCIT	or voicine.	T Granditt ago	-,
	U								
	٥					1			
_	-								
	v					,	\		
_									
	w						1	\	
								1	
_								1	
	×							/	
	L	<i>X</i>	no Otton ac	reas tron	D 6 707 05(a) \				
ate	DY MI	nis reference is not being furnished with 4-YYYY format are publication dates. Cl	assilications may	be US or fi	oreign.			'	
1	retenia DO2	nd Trademark Office (Rev. 01-2001)		Notice	of References	Cited		Part of Pape	NO 20070425
	-002	(1101.01.001)							1

Not Form 1449

	Notice of Reference			- 10/811,056	ZOITUOI NO.	Į F	eexamination	
	Notice of Reference	s Cited		Examiner		- 7	rt Unit	
				Blessing M.	Fuhoro	1	618	Page 2 of 2
$\overline{}$			U.S. P	TENT DOCUM				
\Box	Document Number Country Code-Number-Kind Code	Date MM-YYYY			Name			Classification
	S-2004/0096510	05-2004	Steiner	et al				424489
A	US-2004/0096510 US-8003/0153625	08-2003	Steiner					914/651
В	US-	06-2003	Otomo	01 011				
С	US-		1					/
D			-					/
E	US-							
F			 				/	
G	US-	 . 	<u> </u>					
Н	US-							
-	US-		 			/		
J	US-	J	+			_/		
К	US-	1	├					
L	US-	1				/		
М	US-		FORFICE	PATENT DO	HMENTO			
	Document Number	Date			UMENTS			Classification
	Country Code-Number-Kind Code	MM-YYYY		Country		Name		Classification
N					/			
0					1			
Р								
Q				\setminus				
R			T	Δ				
s								
T					İ			
				ATENT DOCU				
Г	Inclu	rde as applicat	: Author,	Title Date, Pub	lisher, Edition o	r Volume, Pe	rtinent Pages)
1	1							
U					/			
U		_				_		
v		/						
-								
\vdash						/		
-		_				/		
v						/		
v		_					_	
v							<u> </u>	
v w							\ \	
v w	to confined in not being furnished with	this Office action assisteations may	. (See MPE	P § 707.05(a).) reign.				
W X	to religions is not being furnished with CVPG formal are publication dates. Clinghastern Office.	this Office action			Stad		Part of Pa	our No. 2017/16/25
W X copy of thes in MM	his religificat is not being furnished with the profit forms are publication dates. Or of nature, Office (ex. vo. 1-2001)	this Office action		P § 707.05(a).) resgn. of References I	Cited		Part of Pa	per No. 20070425
W X	tis returned is not being furnished with 1970 purpose of the publication dates. Cl Housean Client (91-2001)	this Office action			Cited		Part of Pa	oer No. 20070425
W X appy of the sin MM	ta regulaca to not being luminord with the control of the control	This Office actions may			Cited		Part of Psi	per No. 20070425
W X appy of the sin MM	its religificate is not being luminated with the virtual are publication dates. Ct off nacarma Office Riev. 01-2001)	bus Office action assisticacions may			Cited		Part of Pag	Der No. 38/070428

Not Form 1449

Application/Control No.

Application/Control No.

Reexamination
STEINER ET AL.

Examiner

Art Unit
Page 1 of 2

Chris E. Simmons

	•				/
	_			U.S. PATENT DOCUMENTS	
*	-	Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification 514/44
*	A	US-5, 163,415	06-1998	Sukumar, Saraswati Vaidyanathan	514/510
*	- B	US-5,916 916	06-1999	Hauser et al.	
\vdash	С	US-			
	D	US-	 		
	E	US-			
L	F	US-	 		
-	G H	US-			
-	+	US-			
	1	US-	1	-	
	К	US-	1		
	L	US-	+		
1	M	US-		FORFIGN PATENT DOCUMENTS	

	M.	US-		OREIGN PATENT DO	COMENTS	
			Date		Name .	Classification
*		Document Number Country Code-Number-Kind Code	MM-YYYY	Country		
			10-1998	WIPO	Neubauer et al.	
1	N	WO/1998/045288	10-1000			
	0			1		
-	-		1	X		
_	Р					
١	Q					
Г	R		 	/		
	s		-	1		
-	+-			1		
_	1			NON-PATENT DO	DMENTS	Donne)
		Incl	ude as applicat	ole: Author, Title Date, P	ublisher, Edition or Volume, Pertinent I	- agos,
1 +						

L	_	-	alial Neoplasia": Eur. Urol. 1996;30(2):269-78.)
-		0	Nelson et al. (abstract only, "Chemoprevention for Prostatic Intraepithelial Neoplasia", Eur. Urol. 1996;30(2):259-78.)
-		٧	Formulary Additions, May, 1998 ('Raloxifene (Evista) 60 mg Tablets', Pharmacy Key: A Publication of the Pharmacy and Therapeutics Committee: Formulary Additions: http://www2.kumc.edu/druginfocharmkey/pharmkey/051498.html.)
-		w	Frolik vs.l. ("Time-dependent changes in biochemical bone markers and serum changes in in ovariectomized rats: Effects of ratoxifies HCI, tamoxifies, estrogen, and alendronate", June 1996; Bone; 18(6):821-62()

Sato et al. ("Ratoxifene: a selective extrogen receptor modulator"; Journal of Bone and Mindgal Metaboism; (1994); 12(Suppl.

2):S9-S20.)

Stoy of this reference is not being turnished with this Office action. (See MPEP § 707.05(a).)

first in MM-Y-YY formal are publication dates. Classifications may be US or foreign.

U.S. Palent and Tredemark Office PTO-892 (Rev. 01-2001) Notice of References Cited

Part of Paper No. 20071023

/						Applicant(s)/	Patent Under
-	/			Application/Co	ntrol No.	Reexaminati	on
	1	Notice of References	Citad	11/140,255		STEINER ET	AL.
		Notice of References	Chea	Examiner		1614	Page 2 of 2
				Chris E. Simm		1014	
_				U.S. PATENT DOCUME			Classification
Γ	\neg	Document Number Country Code-Number-Kind Code	Date MM-YYYY		Name		Ciaesilication
1	.+	US-					
T E	-	US-					/
+ -		US-					/
+		US-					
+-		US-					
+	F	US-				/_	
+	G	US-				_/	
+-	н	US-				/	
+-	1	US-				/	
+	1	US-					
+-	ĸ	US-					-
+	L	US-					-
-	M	US-					
_	,			FOREIGN PATENT DOC			Classification
Т		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country		lame	Ciessinolion
+	N	Chaire y double the		X			
+	0						
+	-						
+	9		-				
+	R						
+	s			/			-
+	Ť						
	<u> </u>			NON-PATENT DOCU	MENTS	Desired Des	
*		Inc	lude as applicab	ele: Author, Title Date, Put	lisher, Edition or V	lume, Pertinent Pag	jes)
	υ	Fujimoto et al. (*Can We Pr Urologia Internationalis (20	event Prostate 05); 74(4): abs	Cancer? Rationale an tract.)	d Current Status	of Physiate Cance	r Chemoprevention*;
	v						
	W						_
	×	If this reference is not being furnished with the third of the third o	vith this Office actio	n. (See MPEP § 707.05(a).)			\rightarrow
Date	in t Paten	MM-YYYY format are publication dates a and Tredemark Office 2 (Rev. 01-2001)	Classifications ma	Notice of References	Cited	Part of	Paper No. 20071023